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EXAMINER

ROOKE, AGNES BEATA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/775,679

Applicant(s)

FRIEDLER ET AL.

Examiner

Agnes B Rooke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-23,30-38,41-43,46 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-29,39,40,44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election with traverse of Group V (Claims 24-29, 39, 40, 44 and 45) in reply filed on January 24, 2005 is acknowledged. The traversal is on the grounds that the search required for Groups V and VI requires "searching for the common element of a stabilizing molecule, which binds to a site which at least partially overlaps a functional site of a polypeptide." This is not found persuasive because Group V refers to a compound (a stabilizing molecule) and Group VI refers to a method of identification of a stabilizing molecule, and thus a search for those two groups at the same time would be an undue burden on the examiner. The restriction requirement is still deemed proper and is therefore made final.

Claims 1-47 are pending.

Claims 1-23, 30-38, 41-43, 46, and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected claim.

Claims 24-29, 39, 40, 44 and 45 are currently under examination.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP, paragraph 821.01.

This application is a CIP of PCT/GB02/03668 filed on 08/09/2002, which claims foreign priority to the United Kingdom applications 0119557.7 filed on 08/10/2001; 0127917.3 filed on 11/21/2001; and 0210740.7 filed on 05/10/2001.

Objections

In Claims 24-29, 39-40, and 44, the word "stabilising" should be spelled "stabilizing."

In specification , page 42, line 17, the name "FL-CD83" should be "FL-CDB3."

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-29, 39 and 40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims refer to a stabilizing molecule, which is not isolated or purified, and therefore it is in its natural state.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 24, 26, 27 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 refers to "a natural binding partner." The phrase is indefinite, since the natural binding partner can encompass an indefinite number of biological/chemical compounds. The applicant defines in the specification "a natural binding partner" as a

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molecule that specifically binds to the native state of a given polypeptide in vivo in a wild-type cell or organism," however this definition is not satisfactory because the specification does not further define the natural compound and it does not provide any specific examples or further guidance regarding its structure. See page 4 line 14-15 of the specification.

In Claim 26, the Applicant refers to different mutations of p53 polypeptide, however there is no reference to the polypeptide's amino acid sequence.

In Claims 27 and 45, there are no SEQ ID NOs assigned to the CDB3 polypeptide.

In Claims 27 and 45, the name of CDB3 must be spelled out.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-29, 44, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Naumovski et al., "*The p53-binding Protein 53BP2 Also Interacts with Bcl2 and Impedes Cell Cycle Progression at G2/M*," *Molecular and Cellular Biology*, (July 1996), p. 3884-3892.

Naumovski et al. teach the structure of Bcl2-binding protein ("Bbp") that specifically interacts with p53 protein in vivo, where the Bbp necessary requires for its

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binding to the p53 a specific ankyrin repeats and SH3 domain. See Figure 1, page 3886. Figure 3, page 3887 shows binding of Bbp protein to p53. (Claims 24, 25, and 44).

Figure 6, page 3888, shows an amino acid sequence of Bbp, which contains REDEDEIEW amino acid sequence, as part of the SH3 domain necessary for binding of the Bbp protein to p53. The REDEDEIEW amino acid sequence of Bbp protein is identical to the instant invention (Claims 27 and 45).

Therefore, the claims are anticipated by Naumovski et al. because the REDEDEIEW amino acid fragment of Bbp protein is identical to Claims 27 and 45 of the instant invention, and the amino acid fragment has the same function of binding p53 domain.

Claim 26 is included in the rejection because the structure of p53 is known and the mutations R175H, G245S, R248Q, R249S, R273H, R282W, and I195T are well known in the prior art, as pointed out by the Applicant. See specification, page 1, line 21-26, and page 2, line 1-8.

Claims 28 and 29 are included in this rejection because the stabilizing molecule is a polypeptide, and therefore it would contain, for example, a protein, polypeptide, peptide (Claim 28), and for example, an amine or amide (Claim 29), as its intrinsic characteristic.

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Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Kopchick et al. (U.S. 5,681,809).

Kopchick et al. teach growth hormone receptor antagonists. The GH antagonist is considered to be a stabilizing agent, which binds to the GH polypeptide functional site. See column5, line 37-43, and Abstract.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24, 28, and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Winnacker et al. (U.S. 6,451,541, foreign priority, May 14, 1996).

Winnacker et al. teach chaperones Hsp60 that bind to prion protein PrP^C. See column 2, line 20-34. Also, Winnacker et al. teach that prior art chemical chaperones, such as glycerol, trimethylamine N-oxide, and DMSO stabilize PrP^C and prevent its conversion to PrP^{Sc}. See column 3, line 16-24.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 USC 103(c) and potential 35 USC 102(e), (f) or (g) prior art under 35 USC 103(a).

Claims 24, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naumovski et al. in view of Nandabalan et al. (U.S. 5,977,311).

The teachings of Naumovski et al. are disclosed above. Naumovski does not teach Bbp, which is bound to a fluorophore, e.g. fluorescein.

Nandabalan et al. (U.S. 5,977,311) teach that proteins are routinely labeled with a radioligand, such as fluorescent ligand, e.g. fluorescein, for screening purposes. See column 54, line 55-60.

Therefore, it would have been obvious for a person of ordinary skill in the art to label a stabilizing molecule of Naumovski et al. using the fluorescent ligand of

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Nandabalan et al. because Nandabalan et al. teach that labeling proteins with fluorescein is a conventional method used in screening proteins. Therefore, one would be motivated to label a stabilizing molecule, which binds to the p53 protein with a fluorescein, since the labeling method has been shown to be easy and successful in the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished applications is available through Private PAIR or Public PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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